

952113



DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

February 14, 2005

Our Reference: FEI 3003370957

John Le, President  
Seafood Connection, Inc.  
1979 Monterey Road, Suite 110  
San Jose, California 95112

**WARNING LETTER**

Dear Mr. Le:

On December 7 and 8, 2004 and January 10, 2005, we inspected your seafood facility located at 1979 Monterey Road, Suite 110, San Jose, California. We conducted this inspection to determine your compliance with FDA's seafood processing regulation, Title 21 Code of Federal Regulations, Part 123. The Seafood Hazard Analysis and Critical Control Point (HACCP) regulation was issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). You can find this Act and the Seafood HACCP regulation through links in FDA's home page at <http://www.fda.gov>.

We found that your firm has a serious HACCP deviation. This deviation caused the following fish and fishery products to be adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4), in that the fish had been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health:

- Frozen Pony Fish, Silver Croaker, Spotfinned Bigeye, and Threadfin Bream from [REDACTED]
- Frozen Round Scad, Octopus, Cuttlefish, and Milkfish Sausage from the [REDACTED]

Your serious deviation was as follows:

- You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen pony fish, silver croaker, spotfinned bigeye, and threadfin bream manufactured by [REDACTED] and frozen round scad, octopus, cuttlefish, and milkfish sausage manufactured by [REDACTED]

The above-identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and the requirements of the federal regulations.

You should take prompt measures to correct the deviation. Failure to promptly correct the deviation noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood without examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct the violation, including an explanation of each step taken to prevent its recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara J. Cassens", is written over the typed name.

Barbara J. Cassens  
District Director  
San Francisco District